From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Spring 1996 Volume 3, Issue 2

FDA Issues Proposed Final MQSA Regulations

On April 3, 1996, the Food and Drug Administration (FDA) published the final MQSA regulations as proposals in the *Federal Register.* When these proposals become final, they will replace the interim MQSA regulations that have been in effect since February 1993.

By now, each FDA-certified facility and organization or individual on our MQSA mailing list should have received a copy of the April 3 *Federal Register.*

The agency requests all who are interested to carefully review the new proposals and provide comments by July 2, 1996, which is the end of the 90-day comment period. Address your comments on the proposed rules to:

Dockets Management Branch
(HFZ-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

FDA will carefully consider all comments received by July 2, 1996, as it rewrites the regulations in final form.

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From the Editor…

This issue's headline news is publication of the proposed final Mammography Quality Standards Act (MQSA) regulations in the **Federal Register.** *The proposal and the importance of sending us your comments are addressed in the article that begins at the top of this page and in the "From the Director" column on page 2.*

Making sure you get the **Federal Register** *and other MQSA documents is a high priority for us. To expedite mailing label changes, we have a new address and fax number for reporting address changes. If your mailing label has no accreditation body initials in the upper-right hand corner, send your changes to:*

MQSA
c/o SciComm, Inc.
P.O. Box 30224
Bethesda, MD 20824-9998
Fax 301-986-8015

Also, please send any requests for MQSA-related documents, including the proposed final regulations, to the above address or fax number.

If you wish to change your official "facility" name or address, please notify your ***accreditation body.*** *The accreditation body will forward changes directly to FDA.*

Your questions about certification and inspection should be directed to:

Mammography Quality Assurance Program
Phone 800-838-7715
Fax 410-290-6351

Comments about or suggestions for **Mammography Matters** *should still be sent to:*

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850
Fax 301-594-3306

If you haven't yet received your copy of the April 3, 1996, ***Federal Register***, contact:

MQSA
c/o SciComm, Inc.
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Fax 301-986-8015

What's Inside

From the Director . . .

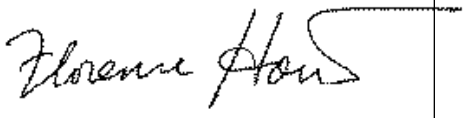
The Food and Drug Administration has published proposals for final regulations under MQSA! These proposals are simply that: proposals.

We've already mailed your facility a copy of the **Federal Register** *containing the proposed regulations. Now it's time for you to comment on the proposals. Please know that your opinions are important. Although FDA has worked with its National Mammography Quality Assurance Advisory Committee (NMQAAC) to develop the proposals, we know you are the missing ingredient to further improve mammography quality. Your opinions will help assure that the regulations we write are attainable, will advance mammography quality, and are reasonable. We're encouraging manufacturers and industry to send us their comments, as well.*

Our proposals are truly open, and we want to hear your thoughtful suggestions. We also need to know what proposals you think are just great. Please give us your positive and negative feedback so we can weigh all comments carefully.

After the comment period is over on July 2, 1996, FDA will meet with the NMQAAC to review comments and gather advice from the members on issues. We'll then revisit those proposals needing changes and redraft them into final regulations.

Final regulations won't be issued for another year or so. In addition, the final regulations, once published, will not become effective immediately because we'll give facilities time to become familiar with them. FDA will then revise its inspection procedures to reflect the final regulations.



Florence Houn, M.D., M.P.H., Director, Division of Mammography Quality and Radiation Programs

List of Certified Mammography Facilities Available from NTIS

A computer diskette with a complete list of all FDA-certified mammography facilities is now available to the public from the National Technical Information Service (NTIS). The diskette, which is sold either as a subscription (updated quarterly) or a single issue (most recent update), includes each facility's name, address, phone number, and accreditation body.

To order a subscription, call 703-487-4630 or fax a request to 703-321-9467. The NTIS order number is SUB-5386. The U.S. price is $195 for four diskettes.

To order a single issue, call NTIS Sales at 703-487-4650 or fax your request to 703-321-8547. The NTIS order number is also SUB-5386, but specify "single issue." The U.S. price for one diskette is $55; the order number is Code D01.

Requests can also be mailed to the U.S. Department of Commerce, Technology Administration, NTIS, 5285 Port Royal Road, Springfield, VA 22161.

The listing is in the file "PUBLIC.ASC." It will be sent on a 3-1/2" DOS diskette in ASCII format. Customers must provide their own search and retrieval software.

Requests for the FDA-certified mammography facilities list should **not** be referred to FDA's Freedom of Information Office. The list is public information.

Introducing Our MQSA Inspectors

MQSA, with its facility inspection program, was envisioned as a system of checks and balances. The law was enacted to assure baseline quality standards so that breast cancer would more likely be detected early, with the end goal of reducing breast cancer mortality.

Accreditation by an approved body, certification by FDA, survey of a facility by a qualified medical physicist, and inspection by a certified inspector are all parts of the system. Although there is overlap among the responsibilities of the various players, none fully replicates another and each has its own unique purpose. The role of the accreditation body under MQSA was covered in the January-February 1996 issue of *Mammography Matters*. In this and future issues, we will examine the roles of the inspector and medical physicist, and revisit them on a more personal level.

Inspectors in training during Course III, November 1994, practice evaluating phantom images and working with a film processor. From left to right: Ken Traegde, MA, Joy Roberts, NC, and Gayle Keane, IA.

The Inspector's Role

MQSA inspections have now been underway for a little more than a year. However, state and federal radiological health inspectors have been on the job for many years, inspecting general radiological units and, since the early 1980s, inspecting mammography equipment. With few exceptions, the states have radiological health programs that have grown to specifically include mammography coverage. Of the approximately 220 MQSA inspectors certified through April 1996, 183 came from state programs, averaging more than 10 years of radiological health experience.

Most, if not all, state inspections include equipment measurements presently performed during the MQSA inspection. MQSA inspectors check for x-ray field and compression paddle alignment, measure half-value layer (HVL) and darkroom fog, evaluate processing, determine average glandular dose, and score a phantom image. They also check through paperwork in a variety of areas, including reviewing QA/QC records, personnel qualifications, and the physicist survey report, and verifying the existence of the necessary medical records and a medical audit system. Many of these areas are also reviewed as part of the state inspections. A check for the existence of a medical audit system is a new aspect of MQSA inspections.

The Inspector Training Program

Each certified MQSA inspector has passed written and practical examinations in three MQSA courses: Medical Radiation Physics (physics of radiation and biological effects as well as radiation safety); Mammography Facility Quality

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MQSA Inspectors

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Assurance (physics of mammography units, needs of radiologists, and basically all that is needed to produce a quality mammogram and how we survey mammography units); and MQSA Inspection Procedures.

According to Ralph Bunge, M.P.H., MQSA Training Coordinator, who has headed our training program since its inception more than 2 years ago, "MQSA inspectors have gone through extensive and rigorous training in how to perform MQSA inspections. This training includes practice inspections on the eight different mammography units at our training center in Rockville, Maryland, as well as practice reviewing facility records."

Ralph also notes that students must learn how to use laptop computers to enter inspection results into our computerized data system.

More About the Inspectors

MQSA inspectors have said they're proud to have a role in maintaining quality mammography, even though it's a difficult role. They must pursue compliance with regulations without undue hardship to facilities that are likewise aiming for quality. The continuous flow of e-mail and calls to our inspector assistance line attest to the inspectors' desire to achieve the correct balance in difficult or unique situations. That they are often successful is demonstrated by the numerous unsolicited letters of commendation we have received (more than 60 as of April 1996) despite the brief history of the program.

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To deal with the few inspector-related problems we've heard about, we have an Inspector QA Program to handle complaints about inspections and to improve our inspection program. For example, when a facility complains about an inspector's attitude or competency, the incident is thoroughly investigated and appropriate steps taken to resolve the problem. Standard operating procedures are in place to handle all facility complaints and concerns. Any questions about our Inspector Quality Assurance Program may be directed to Kaye Chesemore, M.B.A., at 301-594-5994.

Positive comments, such as the following, however, are typical:

"I was impressed with the entire process and the professional manner (the inspector) displayed...(The inspector) was able to get her information without being intimidating or unapproachable. She acted like a consultant, making sure we understood everything." *(From Gabrielle Pedicelli, M.D., Medical Center Hospital, Chillicothe, Ohio)*

"(The inspector) gave us valuable insight into test procedures performed during the inspection and their results. (She) also helped us to better understand processor-related problems and to better evaluate our phantom images. (Her) suggestions and evaluation will help us to better prepare for future inspections and to ensure we are doing the best possible images for our patients...(Her) demeanor taught us that an inspection can be a learning and beneficial experience, not something to fear."

(From Kathy Inman, RT, and Tammy Cutler, RT, Mount Airy Ob-Gyn Center, Inc., Mount Airy, North Carolina)

Second Year Inspections Underway

In the second year of inspections, we will indicate on the printout of the inspection compliance report whether your inspection revealed any problems repeated from last year. Level 1 and some Level 2 repeat problems may be subject to reinspection.

RTs and Interpreting Physicians: Prepare for October 1, 1996

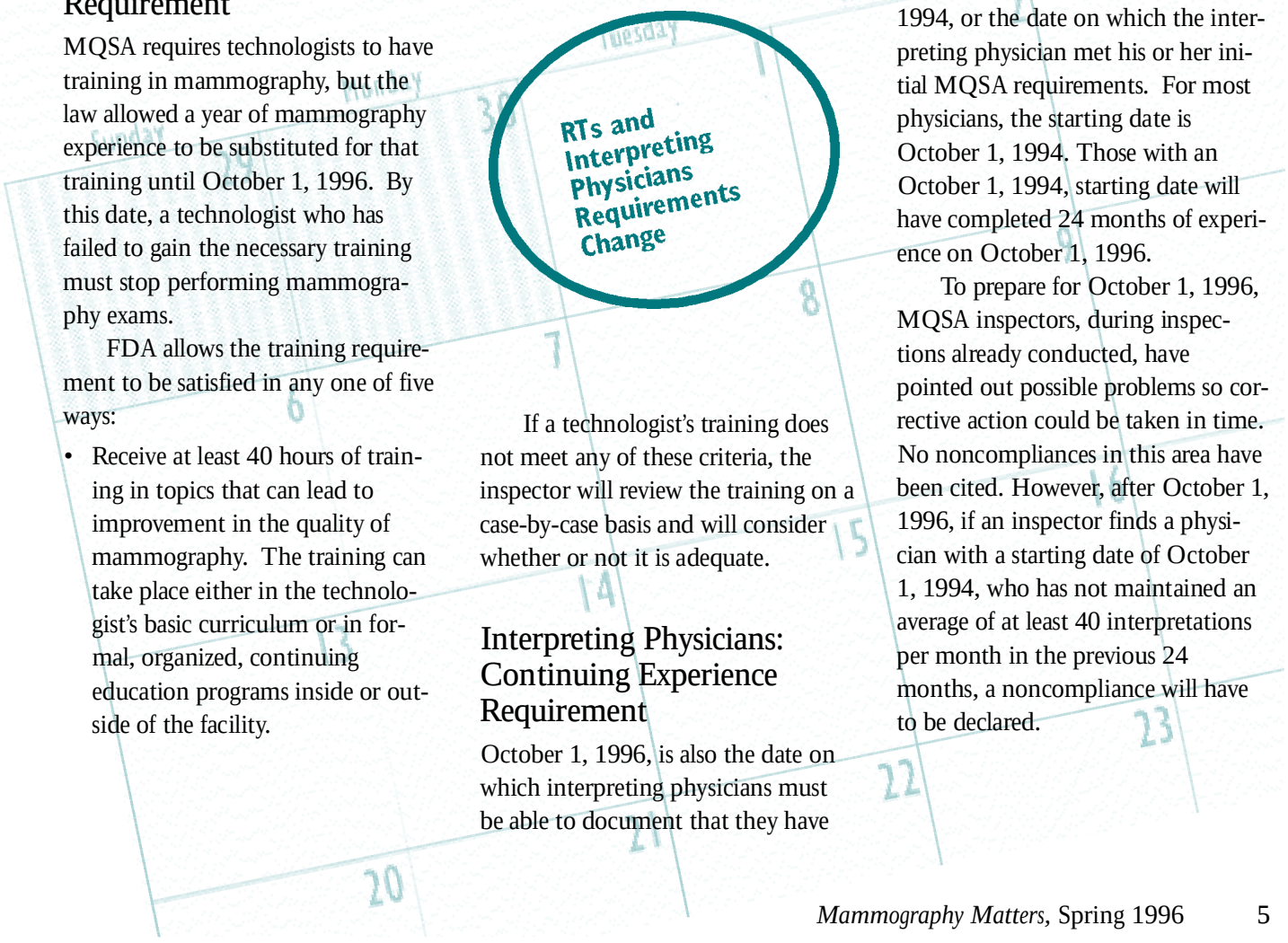
October 1, 1996, is a significant date for mammography personnel. On this date, personnel requirements will change for both radiologic technologists (RTs) and interpreting physicians. For technologists, it is the date when experience will no longer be acceptable as a substitute for mammography training. For most interpreting physicians, it is the date by which they must meet the continuing experience requirement.

Technologists: Mammography Training Requirement

MQSA requires technologists to have training in mammography, but the law allowed a year of mammography experience to be substituted for that training until October 1, 1996. By this date, a technologist who has failed to gain the necessary training must stop performing mammography exams.

FDA allows the training requirement to be satisfied in any one of five ways:

- Receive at least 40 hours of training in topics that can lead to improvement in the quality of mammography. The training can take place either in the technologist's basic curriculum or in formal, organized, continuing education programs inside or outside of the facility.
- Earn the advanced certificate in mammography from the American Registry of Radiologic Technologists.
- Earn the mammography certificate issued by California.
- Earn the mammography certificate issued by Arizona.
- Successfully complete the 3-day course in mammography offered by the Medical Technology Management Institute.



If a technologist's training does not meet any of these criteria, the inspector will review the training on a case-by-case basis and will consider whether or not it is adequate.

Interpreting Physicians: Continuing Experience Requirement

October 1, 1996, is also the date on which interpreting physicians must be able to document that they have maintained an average of at least 40 interpretations per month during the past 24 months. This requirement, which is part of the interim regulations, provided flexibility to allow physicians who stopped interpreting mammograms for a period of time (e.g., for a sabbatical, maternity leave, or rotations into other areas) to perform the necessary number of interpretations by increasing their workload during the remaining months.

The beginning date for meeting this continuing experience requirement is the later of either October 1, 1994, or the date on which the interpreting physician met his or her initial MQSA requirements. For most physicians, the starting date is October 1, 1994. Those with an October 1, 1994, starting date will have completed 24 months of experience on October 1, 1996.

To prepare for October 1, 1996, MQSA inspectors, during inspections already conducted, have pointed out possible problems so corrective action could be taken in time. No noncompliances in this area have been cited. However, after October 1, 1996, if an inspector finds a physician with a starting date of October 1, 1994, who has not maintained an average of at least 40 interpretations per month in the previous 24 months, a noncompliance will have to be declared.

Technical Corner by Orhan Suleiman, Ph.D.

The Technical Corner in **Mammography Matters** *provides facility personnel with helpful hints on various technical and equipment issues involved in meeting MQSA requirements. This section of the newsletter answers inquiries that require too long an answer to be included in the Q & A section.*

Film Processors

Mammography film must be developed properly to ensure the best possible image quality. Proper development means the technologist must adhere to the film manufacturer's recommendations or process the film by a method that results in equivalent performance.

According to the American College of Radiology (ACR) Quality Control Manual, which was incorporated by reference as part of the interim MQSA regulations, the "film-processor-chemical system [must operate] according to pre-established specifications (manufacturer's specifications) or equivalent performance."

This article explains the procedure by which the MQSA inspector evaluates processors. In a future issue, we'll give you additional information and helpful hints to assist you in complying with MQSA processor requirements.

MQSA Inspections: The STEP Test

During the MQSA inspection, the inspector performs the Sensitometric Technique for the Evaluation of Processing (STEP) test on your processor. This test simply compares optical densities of FDA control film developed in your processor to densities obtained on the same control film developed in FDA processors according to each of the major film manufacturers' specifications. The test requires the use of sensitometers and densitometers calibrated to match those at FDA.

Orhan H. Suleiman, Ph.D., Chief, Radiation Programs Branch, Division of Mammography Quality & Radiation Programs

Not only has the FDA control film been processed in different chemistry-processor systems, but so have each of the major mammography films currently in clinical use. Before the film selected as the FDA control film is released to MQSA inspectors, it must demonstrate that it is sensitive enough to detect changes in the chemical solutions of the different film manufacturers.

When the optical densities of the film are equivalent, processing speed is defined as 100. Processing speed is analogous to photographic film speed, where a speed of 100 requires twice as much exposure as a speed of 200. Speed, in this context, is not related to film transport time.

A more detailed description of the STEP test can be found in an article by O.H. Suleiman et al., titled "Automatic Film Processing: Analysis of 9 Years of Observations" (*Radiology* 185:25-28, 1992).

Standard Versus Extended Cycle Processing

"Standard cycle" processing usually refers to a nominal 20-second development time, whereas "extended cycle" processing assumes a nominal 40-second development time. Development time is the time the film is in contact with the developer solution. When standard cycle processing speed is assigned a value of 100, extended cycle processing speed usually ranges between 130 and 140, depending on the type of film.

Noncompliance: What Does This Mean?

Standard cycle processors with a speed less than 80, or extended cycle processors with a speed less than 100, are cited as a Level 2 noncompliance. This means that your processor is deviating significantly from the manufacturer's recommendations.

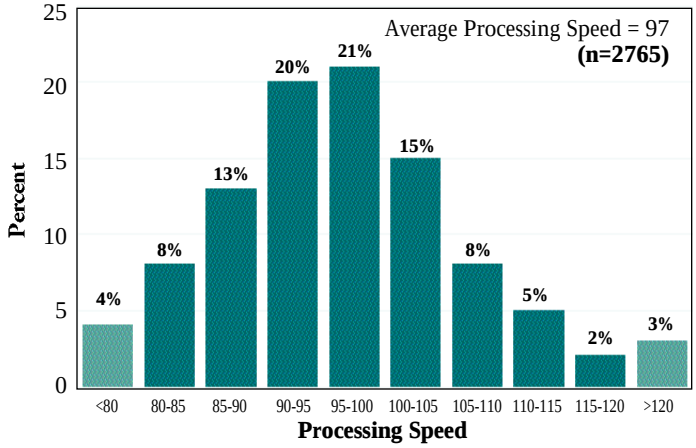
Because the concept of processing speed is new to some facility staff, we are allowing very liberal tolerance during our initial phase of MQSA inspections. A difference of

Technical Corner *(continued)*

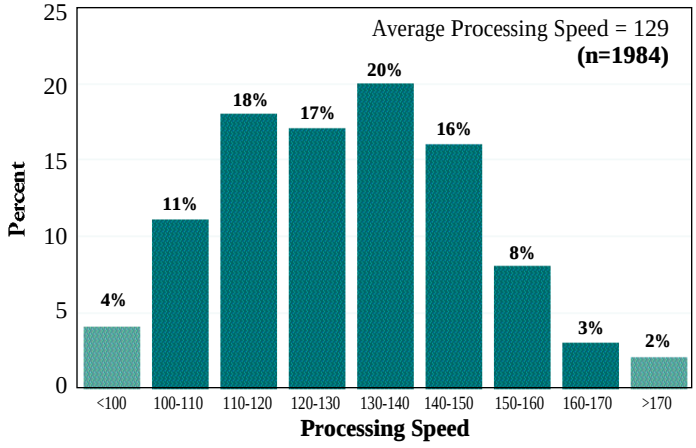
20 percent in relative speed corresponds to a nominal 4-degree Fahrenheit temperature difference. The collective MQSA film-sensitometer-densitometer equipment variability, which is measured by the coefficient of variation (the standard deviation divided by the mean), is 4 percent. Facilities are cited when they deviate by 5 standard deviations from the standard processing speed of 100 or the extended processing speed of 130.

Current MQSA inspections indicate that only 4 percent of standard cycle and 4 percent of extended processors are deviating enough to warrant a Level 2 noncompliance (see the two bar graphs below).

STEP Processing Speed — Standard
(Used by 58% of Facilities)



STEP Processing Speed — Extended
(Used by 42% of Facilities)



Final MQSA Regulations

Continued from page 1

In most cases, the final regulations, which the agency hopes to publish next year, will become effective a year after the publication date. Some of the new equipment regulations will be phased in over a period of years.

Background

The interim regulations, published in December 1993 and amended in September 1994, served as a temporary and streamlined process that made it possible for mammography facilities to meet the October 1, 1994, certification deadline set by Congress. In granting FDA the authority to establish interim regulations, Congress made it clear that final regulations should be established as soon as possible. In response, FDA began working on the final regulations only 2 weeks after publishing the interim regulations.

In developing the proposed regulations, FDA used the advice and comments of its National Mammography Quality Assurance Advisory Committee, information from equipment manufacturers, public comments received in response to the interim regulations, and experience gained during the initial months of implementing the MQSA program.

The proposed final regulations are presented in five separate documents for ease of review. When they are published as final regulations, they will be combined into a single document.

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Final MQSA Regulations

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General Preamble, Proposed Alternative Approaches, and Definitions

This section gives an overview of MQSA, and, to comply with an executive order, sets forth FDA's preliminary ideas for taking an entirely new approach to the development of standards to ensure quality mammography. The new approach would emphasize performance objectives rather than specifying the behavior and manner of compliance.

The definitions section:

- Adds new definitions related to the new requirements and clarifies terms used in the interim regulations.
- Eliminates the definition of "qualified practicing physicians" and "patients" because these terms are no longer needed.

Proposed Final Regulations for Accreditation Bodies

Before mammography facilities can be certified, they must be accredited by an FDA-approved accreditation body. The proposals:

- Set forth a formal procedure for applying to become an accreditation body and make clear what information must be provided.
- Spell out what is needed for an adequate clinical image review, as well as for review of phantom images.
- Clarify the requirements for on-site visits and random clinical image reviews by the accreditation body.
- Outline requirements for accreditation body recordkeeping and reporting.
- Require that accreditation bodies observe a code of conduct, which includes such items as actions to combat health hazards, administration of a quality assurance program, and measures to avoid conflict of interest.
- Require that accreditation bodies establish a system for collecting and resolving serious consumer complaints.
- Formally define the FDA procedures for evaluation and withdrawal of approval of accreditation bodies.

General Facility Provisions

The April 3 *Federal Register* document outlines requirements that facilities must meet. The major differences between the interim and proposed final regulations in this area are that the proposed regulations:

- Add requirements for the content and terminology in the mammography report.
- Add a new requirement that all facilities have a system to provide all examinees with a written notification of mammography results. The medical report, however, would continue to be sent to the examinee's referring health care provider, if there is one.
- Expand the requirements for transfer of mammograms and reports, when requested, and prohibit charging transfer fees that exceed the actual costs.

Some additional new provisions in this section:

- Define the responsibilities of various facility personnel in the quality assurance (QA) program and describe the QA records that must be kept by the facility.
- Require the review of mammography medical outcomes audit data at least every 12 months by an interpreting physician, who will also be responsible for assuring that appropriate corrective actions are taken when needed.
- Set forth new standards for mammography of examinees with breast implants. These standards focus on the training of the personnel involved.
- Require facilities to develop a system for collecting and resolving serious consumer complaints about mammography services. (This section parallels the similar requirement for accreditation bodies.)
- Provide details on the procedures for suspending or revoking facility certificates.

Personnel Regulations

One major difference between the interim and proposed regulations in this document is the added requirements to be met by new interpreting physicians. Other major proposed changes:

- Replace general phrases, such as "training in mammography," which were used to describe the qualifications of technologists who perform mammography, with more specific requirements. The goal is to reduce the uncertainty about the extent and nature of the

qualifications that was evident under the interim regulations.

- Provide a baseline for medical physicist qualifications. This requirement evolved from concern that the existing requirement for board certification or state license or approval led to uneven minimum qualifications.
- Define the process by which individuals, if they fail to maintain compliance with the continuing education and experience requirements, can reestablish their qualifications.
- Add requirements to ensure that individuals have training related to each modality in which they practice.
- Set forth new initial and continuing experience requirements for technologists and physicists in parallel with the existing experience requirements for interpreting physicians.
- Delete the experience alternative to technologist training and the degree-training-experience alternative for initial physicist qualifications found in the interim regulations. These alternatives are being dropped because the time periods established for them under the statute will have expired by the time the final regulations become effective.
- Clarify the requirements for qualification records for facility personnel.

Definitions and Equipment-Related Regulations

The *Federal Register* document includes regulations for equipment and for the portion of the QA program related to maintaining equipment performance. It also defines the terms used in all five documents.

The proposed equipment requirements:

- Replace the general interim requirement that the equipment be "especially designed for mammography" with specific requirements for each component.
- Phase in the new requirements over a 10-year period to reduce costs by lessening the need to replace or retrofit equipment before its normal replacement date.

The proposed QA requirements in this section differ from the interim regulations in that they:

- Do not require the use of a specific QA manual or manuals.
- Indicate specific quality control tests and the frequency at which they are to be conducted.
- Specify action limits and require that quality control test results be analyzed to determine whether problems exist and, if so, that the problems be corrected.
- Set forth requirements for the annual physicist survey of the equipment, tests to be performed on mobile units, and infection control measures.

Mammography Information on the Internet

The April 3, 1996, *Federal Register* notice about the proposed final regulations can be accessed from FDA's home page on the Internet via an Internet browser. Please note that the various browsers display images differently, so the appearance may vary.

To access the appropriate page on the Internet, follow these instructions:

(1) In the URL box on your web browser, type: http://www.fda.gov. This will take you to the FDA home page.

(2) Click your mouse on the following icons that will appear: Medical Devices/Radiological Health; Program Areas; Mammography Quality and Radiation Programs; *Federal Register* Notices.

(3) Select any or all of the five listed April 3, 1996, *Federal Register* documents.

This same procedure may be used to access any mammography-related topic. Go to the Mammography Quality and Radiation Programs page (using the above instructions) and select the area in which you are interested.

You'll need an Acrobat reader to read these files on the screen. To download a reader, select "Free readers for PDF files" from the top of the *Federal Register* page.

Q & A

Q & A is a regular column in **Mammography Matters.** *We welcome your questions and will publish answers to any that are of general interest. Send your questions to* **Mammography Matters,** *FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Fax 301-594-3306.*

Q Will a facility be cited for missing films if a woman wants to have them permanently transferred to another facility?

A No, not if the facility has the woman sign a written release, and the release is in the facility's records.

Q What should a facility do with the medical report if the woman is self-referred and has no health care provider?

A The facility must send the report of the examination to the woman. In addition, a summary written in terms a layperson can understand must be sent to the woman.

Q According to the interim regulations, mammography machines that use screen-film technology must have a provision for operating with a removable grid. Will we be in compliance with MQSA if our machine does not have a removable grid?

A Yes, but only if you have a written (or demonstrable) procedure for performing mammography with and without a grid, and provided that the procedure does not introduce any additional artifacts. For example, if an x-ray machine has a grid that is not removable but allows an exposure to be made by securing the cassette to the top of the patient support for all views, the facility would be in compliance with the removable grid requirement.

The intent of this requirement is to protect the patient from additional and unnecessary exposure to radiation when the imaging technique does not call for use of a grid to optimize image quality (such as a magnification procedure). The key issue is the ability to conduct mammography both with and without a grid.

Q I'm a physician who reads/interprets mammograms. I understand that I have two alternatives for meeting the certification requirements of MQSA. What are they?

A Interpreting physicians can meet the MQSA certification requirements in either of two ways. They can:

- Be certified by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), or the Royal College of Physicians and Surgeons of Canada (RCPSC); these bodies are currently approved by FDA to certify interpreting physicians, *or*
- Have 2 months of documented full-time training in mammography. The best way to document this is to obtain a letter from an official of your residency program.

Q I understand that to meet the continuing experience requirements for interpreting physicians, I must have read and interpreted mammograms from an average of at least 40 exams per month, averaged over a 24-month period, but that this requirement is not yet in effect because MQSA has not been in effect for 24 months. What must I do if I cannot meet this requirement by October 1, 1996, when the 24 months are up and the requirement goes into effect?

A Physicians who fail to meet the continuing experience requirement (to read/interpret mammograms from an average of at least 40 exams per month, averaged over a 24-month period) must read/interpret mammograms from a number of exams (see below) under direct supervision before resuming independent reading. The number of exams that must be read/interpreted *under direct supervision* is the lesser of:

- A number sufficient to bring the physician's average up to 40 exams per month in the previous 24-month period.
- The mammograms from 240 exams.

The *lesser* of the above must be completed within a 6-month period or less. This policy does not change the date on which interpreting physicians met the initial qualifications requirements.

Q & A

Q Can you give some examples of what you mean when you say a physician must read/interpret, under direct supervision, the lesser of a number of exams sufficient to bring the average up to 40 exams per month in the previous 24-month period, or the mammograms from 240 exams?

A Let's assume an interpreting physician has read/interpreted mammograms from an average of only 38 exams per month over the past 24 months. By reading the mammograms from 48 exams *under direct supervision*, the physician will have corrected the noncompliance and may begin reading independently again.

Next, let's assume an interpreting physician has read/interpreted mammograms from an average of only 12 exams per month over the past 24 months. Based on the second criterion in the question/answer above, after reading 240 examinations *under direct supervision* in 6 months or less, the physician will have corrected the noncompliance and may begin reading independently again.

Q I planned to use the mammography CMEs I earned at a major conference to help meet my continuing education requirement under MQSA. Since the conference took place after October 1, 1994, I knew that I couldn't attest to the training and planned on using the certificate issued by the conference organizers as the necessary documentation. The documentation, however, does not break down the numbers of hours among the several areas covered by the conference. Because the certification doesn't show the number of hours in mammography, how can I prove how many I earned? I have contacted the conference organizers, but they have no record of my number of hours in mammography.

A In situations like this, we will permit a limited use of attestation beyond the October 1, 1994, cutoff date. For such meetings, you would need documentation showing the total number of CMEs earned (a certificate or letter, for example) and documentation showing the number of CMEs you could have earned in mammography (such as an agenda or letter). If you have this documentation, you can attest via the FDA-recommended form to the number of mammography CMEs you actually received.

In the long run, we hope that, as a service to their attendees, organizers of conferences covering several areas will provide a breakdown by area of CMEs received.

Q As the quality control technologist for our facility, I perform the monthly phantom image quality test, which is also performed by our physicist during part of the annual survey. I'm puzzled because the scores I obtain during the monthly tests tend to be higher than the score obtained by the physicist. I have asked our radiologist to score my phantom images also, and his scores agree with mine. Last month we had an MQSA inspection and the inspector's phantom image score also was lower than ours. Do you have an explanation?

A It's possible that some of the differences among scores result from a change in operating conditions among the tests. A more likely explanation is that the ACR manuals call for the physicist to use a more sophisticated scoring system for phantom image than is recommended for QC technologists. The instructions to the physicist require deductions from fiber, speck, or mass scores if these artifacts are present. The instructions to technologists, in contrast, require only that the presence of artifacts be noted. Be aware that the inspectors have been trained in the physicist scoring method and use that method for determining compliance with the regulations.

Accreditation, Certification, and Commercial Products

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

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